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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,869	12/09/2003	Carl D. Wahlstrand	1023-318US01	6690
28863 7590 03/08/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/731,869

Applicant(s)

WAHLSTRAND ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 33-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 33-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/18/06 & 10/18/06 & 11/03/06 & 1/30/07
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 10, filed 9/13/06, with respect to the rejection(s) of claim(s) 1-31 and 33-57 under Kraska et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Berrang et al.(US 6,358,281 B1).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

1. Claims 1-31 and 33-57 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638(US Patent Publication 20040176817 A1).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

2. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/730,878 (US Patent Publication 20040176816 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess at least two interconnected modules, each of the modules comprising a housing; and an overmold that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,699 (US Patent Publication 20040172090 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess at least two modules, each with a housing and coupling between the modules, wherein the coupling module permits motion of the two modules along at least one axis of motion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-54 of copending Application No. 10/730,873 (US Patent Publication 20040176814 A1). Although the conflicting claims are not identical, they are not patentably distinct from

Art Unit: 3762

each other because both implantable medical devices possess a plurality of interconnected modules each with a housing and an overmold that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/731,867 (US Patent Publication 20040176673 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a plurality of interconnected modules with housings and an a flexible overmold concave along at least one axis that at least partially encapsulates each of the housings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-31 and 33-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 14-16 of copending Application No. 10/731,868 (US Patent Publication 20040173221 A1).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both implantable medical devices possess a first module that includes control electronics within a first housing, a second module that includes a second housing and a flexible overmold that at least partially covers the first and second housings.

Art Unit: 3762

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 12, 21 and 53 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing claim 12, "device is implanted" to --adapted to be implanted-- and claims 21 and 53, "shaped for implantation" to --is adapted to be shaped for implantation--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3762

1. Claims 1-4, 6-9, 11-25, 27-30, 33-49, 51-54 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. (US 6, 358, 281 B1). Berrang et al. discloses a first and second modules disposed within corresponding first and second housing in addition to the pliable (or bendable) bridge, which the examiner considers to be an overmold, that partially encapsulates the substantially cylindrical first and second housing as depicted in figure 1. The pliable (or bendable) bridge allows "the surgeon to bend said bridge so as to better fit the two housing sections to the curved surface of the skull"(col. 3, lines 35-37). Therefore the pliable bridge has a plurality of degrees of freedom. The examiner considers the first module to be housing 3, which contains the electronics 21 as seen in figure 2. The examiner considers the second module, to be housing 2, which contains the rechargeable battery 18.

In addition to the two modules in the overmold there is also an additional module, a housing for the coil 4 as seen in figure 1. Figures 15-18 depict the two modules and the third module, containing the coil, in alternative embodiments of linear and triangular structure. In the triangular configurations, as depicted in figures 15 and 16, the third module, coil 4, is connected to the overmold by a flexible tether.

In figure 1, "the housing sections 2 and 3 and bridge structure 6 are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof"(col. 9, lines 58-62). Therefore the overmold does comprise at least two materials, e.g. one being gold and the other being silicone. 33

Art Unit: 3762

Also seen in figure 1, the proximal end of lead 8 connects to the lead connection module disposed within the overmold. The connection is between the bridge 6 and the lead junction 16. Lead 8 also has an electrode 10 disposed at the distal end.

As to claims 22, 38, 41 and 54, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 55 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berrang et al. (US 6, 358, 281 B1). Since Berrang et al. discloses a totally implantable system, it would necessarily include a pulse generator that is associated with the electronics 21.

In the alternative, Berrang et al. discloses the claimed invention except for the pulse generator. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electronics as taught by Berrang et al. with a pulse generator since it was known in the art to employ pulse generators in a completely implantable system, specifically auditory stimulation devices.

2. Claims 5, 10, 26, 31, 50 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. (US 6, 358, 281 B1). Berrang et al. discloses the claimed invention except for a recharge coil that encircles both modules. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the coil around the two modules, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04)

As to claims 10, 31, 50 and 57, Berrang et al. et al. discloses the claimed invention except for the helix tether. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Berrang et al. with a helix shaped lead since it was known in the art that helix shaped leads reduce the slack in the lead.

Art Unit: 3762


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alyssa M Alter
Examiner
Art Unit 3762



GEORGE R. EVANISKO
PRIMARY EXAMINER

3/5/7